

Claims

1. Pharmaceutical composition for peroral administration comprising
  - (a) a cyclosporin or macrolide as active ingredient, and
  - (b) a polyethoxylated saturated hydroxy-fatty acid.
2. A composition as claimed in claim 1 containing additionally
  - (c) a C<sub>2</sub>-C<sub>3</sub>-alcohol having one or two hydroxy groups.
3. A composition as claimed in claim 1 or claim 2 containing additionally
  - (d) mono-, di- and/or triesters of fatty acids.
4. A composition as claimed in claim 1, 2 or 3 containing additionally
  - (e) ricinoleic acid glyceride(s) together with smaller proportions of multiply unsaturated fatty acid glycerides or castor oil.
5. Composition as claimed in claim 1 wherein component b) is present as sole surfactant.
6. Pharmaceutical composition according to claim 4 consisting solely of active ingredient (a), and components (b), (d) and (e).
7. Pharmaceutical composition according to any preceding claim in the form of a hard gelatin capsule preparation.
8. Pharmaceutical composition as claimed in any of claims 1 to 6 in the form of a soft gelatin capsule preparation.
9. Pharmaceutical composition as claimed in claim 2, 3 or 4, characterised in that components (a), (b) and (c) are present in a weight ratio of 1 to 4 parts by weight (a) : 6 to 15 parts by weight (b) : 3 to 12 parts by weight (c).

10. Pharmaceutical composition according to claim 2, 3, 4 or 9, wherein the active ingredient is present in the form of cyclosporin A, ([3'-desoxy-3'-oxo-MeBmt]<sup>1</sup>-[Val]<sup>2</sup>-Ciclosporin), rapamycin, 40-0-(2-hydroxy)ethyl rapamycin, 32-deoxorapamycin, 16-pent-2-ynyloxy-32(S)-dihydrorapamycin, FK 506, 33-epi-chloro-33-desoxy-ascomycin, the compound disclosed under Example 6d and Example 71 in EP 569 337, or the compound disclosed under Example 8 in EP 626 385;
- component (b) in the form of polyethylene glycol-660-12-hydroxy-stearate, and component (c) in the form of ethanol or 1,2-propylene glycol.
11. Pharmaceutical composition according to claim 10, characterised in that components (a) : (b) : (c) are present in a capsule in a weight ratio of 5 : 65 : 28.
12. Use of polyethylene glycol-660-12-hydroxy-stearate and ethanol, or 1,2-propylene glycol, in the production of medicinal preparations containing one or more cyclosporins or macrolides as active ingredient for peroral administration.
13. Pharmaceutical composition as claimed in any one of claims 1 to 11 in the form of optionally coated or glazed tablets as a unit dosage form.
14. Use according to claim 12, characterised in that the pharmaceutical composition is produced in unit dosage form as tablets, or soft- or hard gelatin capsules.
15. Use of carrier substances and excipients according to any preceding claim for the production of a medicinal preparation containing a cyclosporin or a macrolide, for immuno-suppressive, anti-inflammatory or anti-parasitic treatment in human and veterinary medicine.

16. Use as claimed in claim 15 for treatment of organ or tissue transplant rejection.
17. Composition as claimed in any one of claims 1 to 11 or claim 13 wherein the polyethoxylated saturated hydroxy fatty acid is obtainable by reacting a saturated hydroxy fatty acid with ethylene oxide.
18. Composition as claimed in any one of claims 1 to 11 or claim 13 wherein the polyethoxylated saturated hydroxy fatty acid is obtainable by reacting a saturated hydroxy fatty acid with polyethylene glycol.
19. Pharmaceutical composition for peroral administration comprising
  - (a) a cyclosporin, e.g. cyclosporin A, as active ingredient, and
  - (b) a polyethoxylated saturated hydroxy-fatty acid, and optionally
  - (c) a C<sub>2</sub>-C<sub>3</sub>-alcohol having one or two hydroxy groups, and optionally
  - (d) mono-, di- and/or triesters of fatty acids, and optionally
  - (e) ricinoleic acid glyceride(s) together with smaller proportions of multiply unsaturated fatty acid glycerides or castor oil.
20. Compositions substantially as hereinbefore described with reference to the Examples.